by the Examiner in the Advisory Action. Accordingly, this Preliminary Communication and RCE are being timely filed.

**REMARKS**

Claim 89 is pending and under examination in the subject application. No claim has been added, canceled, or amended herein. Accordingly, claim 89 is still pending and under examination.

In view of the remarks below, applicant maintains that the Examiner's rejections and objection have been overcome, and respectfully requests that they be withdrawn.

**Rejection Under 35 U.S.C. §101**

The Examiner rejected claim 89 under 35 U.S.C. §101 as allegedly not supported by a specific asserted utility or a well-established utility.

In response, applicant respectfully traverses the Examiner's rejection.

Claim 89 provides an isolated human MUM-1 protein and a fragment thereof. As detailed in the subject specification, the over-expression of the MUM-1 gene, i.e., over-expression of MUM-1 mRNA, correlates with multiple myeloma.

The Examiner asserts that a positive correlation between mRNA over-production and over-expression of the MUM-1 protein would not be reasonably expected. The Examiner cites Anderson, et al. in support of this assertion.

In response, applicant maintains that Anderson et al. teaches a positive correlation of .48 on a scale where 1.0 represents a perfect correlation and 0.0 represents no correlation (page 535, first column). According to M.P.E.P. §2107.02(VII), "the applicant does not have to provide evidence such that it establishes an asserted utility is true 'beyond a reasonable doubt.'" *In re Irons,* 340 F.2d 974, 978, 114 USPQ 351, 354 (CCPA 1965). "Nor does an applicant have to provide evidence such that it establishes an asserted utility as a matter of statistical certainty." *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980). Therefore, applicant maintains that a positive correlation is sufficient to support a specific and credible utility for the instant MUM-1 protein and fragment thereof.

Nevertheless, applicant notes that over-expression of the MUM-1 protein in fact accompanies over-production of its corresponding mRNA. As evidence, applicant submits, as Exhibit A, Iida, et al., (1997) "Deregulation of MUM-1/IRF4 by chromosomal translocation in multiple myeloma", Nature Genetics, 17:226-230. On page 228, last paragraph, Iida et al. state that "increased RNA expression was associated with increased levels of MUM1/IRF4 protein expression" and conclude that "these results indicated that the functional consequence of chromosomal translocation is the deregulation of MUM-1/IRF4 gene expression, leading to the production of *increased* amounts of functional MUM-1/IRF4 protein" (emphasis added). In view of Iida, et al., applicant maintains that over-expression of MUM-1 protein has been shown to positively correlate with multiple myeloma, based on the observed correlations between MUM-1 protein over-expression and mRNA

over-production, and between mRNA over-production and the disease state.

In view of the above remarks, applicant maintains that the claimed MUM-1 protein and fragment have a specific and credible utility, and that claim 89 satisfies the requirements of 35 U.S.C. §101.

**Rejection Under 35 U.S.C. §112, First Paragraph**

The Examiner rejected claim 89 under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. Specifically, the Examiner maintains that one skilled in the art would not know how to use the claimed invention. The Examiner's rejection is based on the Examiner's assertions set forth in support of the rejection under 35 U.S.C. §101.

In response, applicant respectfully traverses the Examiner's rejection for the reasons set forth above in response to the rejection under 35 U.S.C. §101, and maintains that given the utility of the claimed invention, one would know how to use it.

In view of the above remarks, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §112, first paragraph.

**Objection Under 35 U.S.C. §132**

The Examiner objected to applicant's Amendment of September 17, 2001 under 35 U.S.C. §132 as allegedly introducing new matter into the disclosure. Specifically, the Examiner

asserted that the phrase "a fragment thereof" recited in claim 89 with respect to MUM-1 protein constitutes new matter.

In response, applicant respectfully traverses the Examiner's objection.

Applicant directs the Examiner's attention to M.P.E.P. §706.03(o) which states in pertinent part: "If new matter is added *only* to a claim, an objection using this paragraph should *not* be made" (emphasis added). The September 17, 2001 Amendment amended only claim 89. Therefore, the objection under 35 U.S.C. §132 is not proper.

Moreover, applicant maintains that the phrase "a fragment thereof" is supported by the disclosure. Support may be found *inter alia* at page 12, line 25, which refers to each restriction "fragment" within the MUM-1 coding region, shown in Figure 7 of the disclosure.

Applicant directs the Examiner's attention to Figure 7, which illustrates the genomic organization of the MUM-1 gene showing specifically the coding region for the MUM-1 protein claimed in the subject application. Specifically, Figure 7 shows a restriction map of the MUM-1 gene. A person skilled in the art would recognize the MUM-1 fragments encoded by the restriction fragments shown therein, and be able to use the restriction map to generate fragments of MUM-1 protein through techniques well known in the art at the time of filing of the subject application.

To underscore his position, applicant further directs the Examiner's attention to the illustration attached hereto as

Exhibit B. Exhibit B sets forth, at top, the relevant portion of the MUM-1 restriction map shown in Figure 7 of this application. The MUM-1-encoding sequence begins with the codon marked "ATG" and ends with the codon marked "TGA." Below the restriction map is set forth, for clarity, an expanded schematic of the restriction map of MUM-1-encoding nucleic acid, with H1-H3, B1 and B2, and E1-E5 denoting restriction endonuclease cleavage sites. Below the expanded schematic are shown the MUM-1 fragment-encoding sequences of plasmids designated "λMUM1-3b", "λMUM1-15" and "λMUM1-3." Finally, Exhibit B sets forth a schematic illustration of some of the nucleic acid fragments which would be expected to result from the various permutations of restriction endonuclease cleavage. These fragments are numbered from 1-69. Applicant notes that each of nucleic acid fragments 1-69 schematically shown constitutes support for the MUM-1 fragment encoded thereby.

Fragments 1-69 have as boundaries the following termini, set forth in parentheses: fragment 1 (N-terminus-H1), fragment 2 (N-terminus-B1), fragment 3 (N-terminus-E1), fragment 4 (N-terminus-E2), fragment 5 (N-terminus-E3), fragment 6 (N-terminus-H2), fragment 7 (N-terminus-E4), fragment 8 (N-terminus-E5), fragment 9 (H1-B1), fragment 10 (H1-E1), fragment 11 (H1-E2), fragment 12 (H1-E3), fragment 13 (H1-H2), fragment 14 (H1-E4), fragment 15 (H1-E5), fragment 16 (B1-E1), fragment 17 (B1-E2), fragment 18 (B1-E3), fragment 19 (B1-H2), fragment 20 (B1-E4), fragment 21 (B1-E5), fragment 22 (E1-E2), fragment 23 (E1-E3), fragment 24 (E1-H2), fragment 25 (E1-E4), fragment 26 (E1-E5), fragment 27 (E2-E3), fragment 28 (E2-H2), fragment 29 (E2-E4), fragment 30 (E2-E5), fragment 31 (E3-H2), fragment 32 (E3-E4), fragment 33 (E3-E5), fragment 34 (H2-E4),

fragment 35 (H2-E5), fragment 36 (H1-C-terminus), fragment 37 (B1-C-terminus), fragment 38 (E1-C-terminus), fragment 39 (E2-C-terminus), fragment 40 (E3-C-terminus), fragment 41 (H2-C-terminus), fragment 42 (E4-C-terminus), fragment 43 (E5-C-terminus), fragment 44 (H3-C-terminus) fragment 45 (B2-C-terminus), fragment 46 (H1-B2), fragment 47 (B1-B2), fragment 48 (E1-B2), fragment 49 (E2-B2), fragment 50 (E3-B2), fragment 51 (H2-B2), fragment 52 (E4-B2), fragment 53 (E5-B2), fragment 54 (H3-B2), fragment 55 (H1-H3), fragment 56 (B1-H3), fragment 57 (E1-H3), fragment 58 (E2-H3), fragment 59 (E3-H3), fragment 60 (H2-H3), fragment 61 (E4-H3), fragment 62 (E5-H3), fragment 63 (H1-E5), fragment 64 (B1-E5), fragment 65 (E1-E5), fragment 66 (E2-E5), fragment 67 (E3-E5), fragment 68 (H2-E5) and fragment 69 (E4-E5).

Accordingly, applicant maintains that the phrase "a fragment thereof" is supported by the disclosure as filed and does not introduce new matter into the application.

In view of the above remarks, applicant maintains that claim 89 satisfies the provisions of 35 U.S.C. §132 and §112, first paragraph.

**Summary**

In view of the arguments set forth above, applicant maintains that the Examiner's rejections and objections have been overcome. Applicant respectfully requests that the Examiner reconsider and withdraw same, and earnestly solicits allowance of the pending claim.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the RCE fee of $375.00, is deemed necessary in connection with this Preliminary Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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